# Stratton VA Medical Center
## IRB Standard Operating Procedure: Communication

**PURPOSE**

It is the mandate, authority and policy of the IRB to ensure the safety of participants in research studies.

**POLICY**

**Reporting between the IRB and the R&D Committees**

In order to fulfill the responsibility of protecting research participants, it is necessary to ensure the flow of critical information between the IRB and the R&D committees in an expeditious manner. The following procedure is established to ensure that this occurs and delineate circumstances when this might be necessary. This limited e-mail string will ensure that only those individuals responsible for responding to reported issues will be apprised of them and reduce the risk of the issues becoming general knowledge at the facility before being fully explored. It will also provide a forum for a continuing dialog among those responsible for acting on these issues.

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**Procedure:**

The following is a list of circumstances where expeditious communication between the IRB and the R&D is necessary. Such communications may include but are not limited to:

- Reportable issues involving research
- Suspension of studies
- Conflicts of interest
- Research non- compliance
- Termination of studies for cause
- Delays of protocol approval due to “approval with modifications”

**Reporting Scheme:**

Circumstances requiring expeditious communication may be reported to the Research Office from any source, including the results of discussions at the IRB meetings.

This information will be communicated to the IRB chair, or designee, to determine whether immediate action needs to be taken to protect research subjects.
The IRB Chair, or designee, will compose an e-mail message to be sent to:

(1) R&D Chair
(2) ACOS-R/R&D
(3) Research Office
(4) Research Compliance Officer, when appropriate

apprising them of the situation and any immediate action taken. Any immediate actions taken will be reported to the IRB for review at the next convened meeting and entered into the minutes. Non-emergent issues will be discussed at the next convened meeting of the IRB and entered into the minutes

**Other expeditious reporting**

Reporting R&D reviews of new protocols for scientific and scholarly validity

(1) in order to facilitate the approval process for new research proposals, reviewers of new research at the IRB and R&D will receive proposals two weeks prior to the IRB Committee meeting
(2) at least one R&D reviewer will report his/her findings to the R&D Chair, who will in-turn, e-mail the HRPP Coordinator with the R&D reviewer's scientific and scholarly evaluation
(3) the HRPP Coordinator will e-mail the IRB reviewers with the R&D reviewer's scientific and scholarly evaluation so that the IRB reviewers may consider their findings in their review of the proposals.

**Multi-site Research Communication**

Investigators conducting multi-site research will, on the "Application to Undertake Research Involving Human Subjects" be required to inform the IRB of:

Whether the site had an IRB
Whether the site had granted permission for the research to be conducted
Contact information for the site [the name and type of off-site facility participating in the study, their

location and contact person (name. telephone and/or e-mail)].
If the site had an IRB, whether the IRB had approved the research or planned to defer review to the organization's IRB

If an off-site IRB has deferred to the organization, obtain a letter so stating for the record
Advise what site will be the IRB of record
If the organization is to be the IRB of record, a letter will be sent to those sites that have deferred to the organization, accepting the responsibility

When the Investigator is the lead investigator of a multi-site study, or the organization is the lead site in a multi-site study, the application needs to include information about the management of information obtained in multi-site research that might be relevant to participant protections and have the IRB evaluate whether the management of information is adequate. Information may include, but is not limited to:

unanticipated problems involving risks to participants or others
Data Safety Monitoring Board (DSMB) reports
Interim results
Protocol amendments

These submissions may be part of a continuing review or reportable events (per SOP IRB-008) that will be addressed by the Chair of the IRB and/or discussed at the full IRB meeting, as appropriate. Any discussion or actions taken will be recorded in the committee.

**Communication between IRBs**

When it becomes necessary for the organization IRB to communicate with an IRB at another site in a multi-site research study, the information provided in 2.2.2 (above), the following procedures should be followed. Reasons for contacting may include, but are not limited to, the off-site's experiences with adverse and unanticipated events at their site, or protocol deviations.

Informal communications between the organization IRB and off-site IRBs may be conducted by telephone or e-mail
More formal communications should be conducted by e-mail so that, when appropriate, a hard copy of the mail string may be generated for the record and included in the minutes of the IRB and entered into the research file

**Dissemination of New Information**

To all research investigators and staff – new information and changes to policies, procedures and forms that may affect the human research protection program will be communicated by the Administrative Officer for R&D/or the research administrative staff. The means of communication may include:

E-mail messages
Website postings
Face-to-face meetings
Telephone conversations
Training sessions
Handout materials